K984361

JAN 13 1999

OSBORN LABORATORIES
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510(k) SUMMARY

Osborn Laboratories
Oral-Eze™ Oral Fluid Collection System

December 4, 1998

Submitter Information:

Osborn Laboratories
19401 West 117th Street
Olathe, Kansas 66062

Submitter's Name: Gilbert P. Bourk III
Phone: (913) 390-7146

Device Name:

Osborn Laboratories Oral-Eze Oral Fluid Collection System

Common Name: Oral fluid collection kit

Classification Name: Blood specimen collection device

Predicate Device Equivalence:

Substantial equivalence is claimed to the Saliva•Sampler® Saliva Collection Device (primary predicate device), cleared for commercial distribution per K942435, and to the EpiScreen™ Oral Collection Device (secondary predicate device), cleared for commercial distribution per K973395 and K970357.

Device Description:

The Oral-Eze Oral Fluid Collection System is a device used by a person under the supervision of a trained health care professional to obtain an oral fluid specimen and have the specimen contained for transport to a laboratory. The device consists of the following:

- A collector pad holder/handle with a collector pad, contained in a sealed "peel-apart" plastic envelope. The collector pad holder/ handle itself consists of two parts, a collector pad holder and a collector pad slider. The collector pad is held in the holder/handle by a pin in the slider that fits into a hole in the collector pad, and by the holder, which keeps the pad from falling off the pin. The slider has a round indicator port in it. A blue color appears in this indicator port when a predetermined amount of oral fluid has been collected.
- An Oral Fluid Collection Tube with a screw-on lid, containing preservative fluid.
- A clear plastic sealed envelope that contains all three of the above items.

Intended Use:

The Oral-Eze Oral Fluid Collection System is a prescription device, intended for use by a person under the supervision of a trained health care professional to collect oral fluid specimens, contain these specimens, and preserve the specimens after collection and during transport from the collection area to the laboratory.

Comparison of Technological Characteristics:

Essentially, the Oral-Eze and Saliva•Sampler devices use the same basic technology, i.e., collecting an oral fluid specimen on a fibrous pad and preserving it in a buffer solution contained in a collection tube. One major difference is that with the Oral-Eze device the collector pad is placed in the buccal cavity, whereas with the Saliva•Sampler the collector pad is placed sublingually. Another major difference is that only the collector pad of the Oral-Eze device is contained in the collection tube, whereas both the handle and collector pad of the Saliva•Sampler predicate device are contained in collection tube. In addition, even though the Oral-Eze device is not sterile and the handle and collector pad of the Saliva•Sampler predicate device are sterile, the handle and collector pad of the secondary predicate device, the EpiScreen Oral Specimen Collection Device, are not sterile.

Summary of Performance Testing:

To assess the suitability of the Oral-Eze Oral Fluid Collection System, both the Oral-Eze device and the Saliva•Sampler predicate device were tested for a number of characteristics, such as specimen collection time and volume collected. The test results demonstrated that the Oral-Eze device is substantially equivalent to the Saliva•Sampler predicate device.

To obtain assurance that the oral fluid specimens would remain stable even after undergoing the extreme temperatures that can be experienced by any object sent by common carrier or by the U.S. Mail, Oral-Eze collection tubes with collector pads containing oral fluid specimens were subjected to environmental testing. The test results were considered to be within acceptable accuracy limits.

Conclusions:

Based on the above, we have concluded that the Oral-Eze Oral Fluid Collection System is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 13 1999

Mr. Gilbert P. Bourk, III
Vice President and General Counsel
Osborn Laboratories
19401 West 117th Street
Olathe, Kansas 66062

Re: K984361
Trade Name: Osborn Laboratories Oral-Eze™ Oral Fluid Collection System
Regulatory Class: II
Product Code: JKA
Dated: December 4, 1998
Received: December 7, 1998

Dear Mr. Bourk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984361

Device Name: _____

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Indications For Use:

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Oral-Eze Oral Fluid Collection System

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Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984361

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)